

Response Under 37 CFR 1.116

Expedited Procedure

Examining Group 3736

Application No. 10/557,286

Paper Dated: July 13, 2009

In Reply to USPTO Correspondence of March 13, 2009

Attorney Docket No. 0470-053534

REMARKS

The final Office Action of March 13, 2009, has been reviewed and the Examiner's comments carefully considered. Claims 13, 18, 19, 21, 22 and 25 have been amended by way of this Amendment. Accordingly, claims 13-25 are currently pending in this application, and claims 13, 19 and 21 are in independent form. Support for the amendments made herein can be found in Figs. 1-3; page 4, line 13 to page 11 of the specification; and original claims 1-12. Applicant respectfully submits that no new matter is being added by way of this Amendment.

Allowable Subject Matter:

Initially, the Applicant thanks the Examiner for indicating that the subject matter of claims 19 and 21 define over the prior art of record. Specifically, the Examiner has indicated that claim 19 is allowable and claim 21 would be allowable if rewritten in independent form including the base claim and any intervening claims. Claim 21 has been amended into independent form including all the limitations of claims 13, 18 and 20.

Claim Objections:

Claims 13, 19, 21, 22 and 25 have been objected to for various minor informalities. These claims have been amended as set forth above to correct these informalities. Claim 18 has been amended in like manner to claim 21 to correct a similar informality. In view of the foregoing amendments, reconsideration and withdrawal of these objections are respectfully requested.

Prior Art Rejections:

Claims 13, 14, 17, 24 and 25 stand rejected under 35 U.S.C. §102(e) for anticipation by U.S. Patent Application Publication No. 2003/0097079 to Garcia (hereinafter "Garcia"). Claims 15 and 16 stand rejected under 35 U.S.C. §103(a) for obviousness over Garcia in view of U.S. Patent No. 6,884,427 to Barrows (hereinafter "Barrows"). Claims 18, 20,

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22 and 23 stand rejected under 35 U.S.C. §103(a) for obviousness over Garcia in view U.S. Patent No. 4,838,280 to Haaga (hereinafter “Haaga”). In view of the foregoing amendments and following remarks, reconsideration and withdrawal of these rejections are respectfully requested.

Independent claim 13, as amended herewith, is directed to an insertion sleeve assembly comprising an insertion instrument for performing a medical operation and a sleeve of bio-absorbable material defining an interior for guiding said instrument. The sleeve has an opening and comprises a stop adjacent the opening. Further, the sleeve is made of a material that is relatively rigid outside the body and becomes softer after introduction into the body and collapses onto itself when the instrument is withdrawn. The stop is configured to abut against an area of patient’s skin surrounding an insertion site so as to prevent skin contamination.

Garcia does not teach or suggest the presently claimed invention and, as such, one of ordinary skill in the art would not look to the teachings of Garcia in order to arrive at the subject matter of the presently claimed invention. Garcia teaches a needle introduction sheath for use when removing a biopsy sample via a needle from an organ, such as a lung, liver, etc. from a body. However, there is no discussion in Garcia regarding what occurs when such biopsy sample actually exits the body and could be exposed to the skin of the body, causing potential contamination to the skin. With Garcia, there is only a rigid tube provided to give protection to the biopsy sample itself. In contrast to Garcia, after introduction of the sleeve and insertion instrument into a body, the sleeve of the present invention extends from the target organ, through intervening tissues and organs, and subsequently, out through the skin of the body. As such, during withdrawal of the insertion instrument, contamination with cells retrieved from the target organ does not occur to the intervening tissues and organs, including the skin of the body. The presence of the stop adjacent the opening of the sleeve of the invention of amended claim 13 abuts against the skin surface of the body, preventing such potential skin contamination.

To the extent that Garcia teaches an upper surface of the sheath (20) acting to prevent further movement of the biopsy needle (24) with respect to the sheath (20), this surface is not configured to abut against an area of patient’s skin surrounding an insertion site so as to prevent skin contamination, as is claimed in independent claim 13. As such, and in light of the

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amendments to independent claim 13, Applicant respectfully requests reconsideration and withdrawal of the anticipation rejection of independent claim 13.

With respect to Barrows, as discussed above, Garcia does not provide for protection of the skin of the body once the insertion instrument is taken out from the body, as is provided in presently amended claim 13. Barrows fails to teach or suggest a physical mechanism for such protection as well. Accordingly, Barrows fails to rectify the skin protection deficiency of Garcia. As such, even if the teachings of Garcia and Barrows were combined, the resulting combination would not teach or suggest all of the claim elements of amended claim 13. Thus, Applicant respectfully submits that independent claim 13, as amended, is patentable and non-obvious over the combination of Garcia and Barrows.

With respect to Haaga, as discussed above, Garcia does not provide for protection of the skin of the body once the insertion instrument is taken out from the body, as is provided in presently amended claim 13. Haaga fails to teach or suggest a physical mechanism for such protection as well. Instead, Haaga is directed to a sheath that is used to minimize bleeding at the biopsy site. Accordingly, Haaga fails to rectify the skin protection deficiency of Garcia. As such, even if the teachings of Garcia and Haaga were combined, the resulting combination would not teach or suggest all of the claim elements of amended claim 13. Thus, Applicant respectfully submits that independent claim 13, as amended, is patentable and non-obvious over the combination of Garcia and Barrows.

Applicant submits that claim 13, as amended, is allowable for at least the foregoing reasons, as the teachings of the prior art of record, including Barrows and Haaga, are not sufficient to overcome the deficiencies in the teachings of Garcia with respect to claim 13.

Claims 14-18, 20 and 22-25 are dependent upon and add further limitations to independent claim 13 and are allowable for at least the same reasons discussed above in connection with claim 13.

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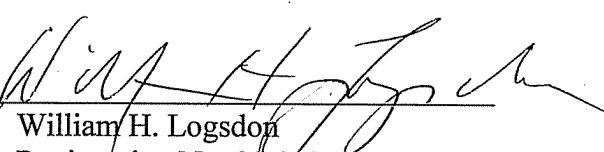
Conclusion:

Based on the foregoing amendments and remarks, reconsideration of the rejections and allowance of claims 13-25 are respectfully requested.

Respectfully submitted,

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